an electro-mechanical transducer excited at the single frequency by the electrical generator, the electro-mechanical transducer joined mechanically to

a longitudinal-torsional resonator excited by the electro-mechanical transducer at [a] at the single frequency for providing combined longitudinal and torsional motion in frequency synchronism, the longitudinal-torsional resonator mechanically joined to a tip shaped for dissecting resistant biological tissue,

a vacuum source connected to said longitudinal-torsional resonator for removal of the dissected resistant biological tissue.

Remarks

The Applicant replies to the second final official action of the United States Patent and Trademark Office of March 26, 2002 with three months to reply ending on June 26, 2002.

It is appreciated that the Examiner has withdrawn the 35 USC 112 rejections. Support for Applicant's amendments to the claims can be found in Applicant's disclosure as filed and figures. Specifically, the independent claims include a single frequency generator to structurally support the frequency synchronism language that was always in the claims. The Examiner in the response to arguments notes that Applicant's removal of hard tissue is unique. The independent claims had been amended in accord with the application as filed. Specifically, support for separating resistant tissue appears in the abstract and the disclosure explains that collagenous tissue, bone and other connective or structurally supportive tissue is treatable.

The Examiner has rejected claims 1-3, 5, 6, 9 and 10 under 35 USC 102(e) as being anticipated by Boukhny, U.S. Patent 6,077,285. The Examiner states that '285 discloses an ultrasonic longitudinal-torsional system comprising

an electrical generator supplying alternating electrical voltage (26), an electro-mechanical transducer excited by the electrical generator (18, 20), a longitudinal-torsional resonator excited by the electro-mechanical transducer (16) and a tip (12, 13). The Examiner argues that Boukhny is capable of performing the function of (providing combined longitudinal and torsional motion in frequency synchronism).

Boukhny '285, fails to disclose structure for and lacks recognition of the usefulness of combined longitudinal and torsional motion at a **single frequency** on difficult to remove biological tissue. Applicant's LT resonators with tips suitably shaped for the separation and removal of resistant biological tissue would not have been required or obvious for phacoemulsification of soft eye tissue.

Applicant has reviewed the '285 reference and respectfully disagrees with the Examiner's assessment of the disclosure thereof as regards anticipation. Boukhny suggests transducers capable of providing longitudinal and torsional motion separately at discrete frequencies, but to do so Boukhny particularly teaches two separate generators and piezo-active sets of materials. While one generator 26 is schematically shown the specific teachings of '285 are directed to separate generators operating at different frequencies to drive one transducer for longitudinal motion and another transducer for torsional motion.

Although evidence of unexpected results must compare the claimed invention with the closest prior reference, Applicant is not required to compare the claimed invention with subject matter that does not exist in the prior reference. If the Examiner merely extracts from structural similarities in the prior teachings of '285 as suggesting that Applicant's single generator would have been obvious without the teaching from Applicant's present application that would be a resort to hindsight. Thus, but for Applicant's disclosed teachings, it would be unreasonable to construe the "structural similarities" of the '285 reference in any way that departs from its specifically disclosed construction and mode of operation. Consequently, the reference alone or combined with another can teach only that which is disclosed or clearly suggested, and not variations

that could only be suspected or imagined, particularly when Applicant's own disclosure is needed to provide the basis for such departure and the resulting conclusions of anticipation or obviousness.

Boukhny is a phacoemulsification system with two crystals driven by what may appear in a schematic figure with no detailed description to be a single generator. Separate frequencies are required in '285 to drive the discrete torsional transducer and discrete longitudinal transducer separately as it states:

> "Crystals 18 and 20 vibrate ultrasonically in response to a signal generated by ultrasound generator 26. Crystals 18 are polarized to produce torsional motion. Crystals 20 are polarized to produce longitudinal motion."
>
> "As seen in FIG. 2, ultrasound generator 26 employs a broad-spectrum source to generate at least a component of the signal that drives an ultrasonic handpiece ("the drive signal"). The broad-spectrum source may be programmable and thus easily adjustable by varying certain input information fed to the source. However, a fixed-spectrum source may also be used without difficulty. A fast fourier transform ("FFT") digital signal processor ("DSP") may be used to analyze the response of handpiece 10 to the broad-spectrum component of the drive signal. In real-time applications, the output of the FFT DSP is used to generate control parameters embodied within an appropriate feedback signal, which is fed to the circuitry generating the drive signal in order to alter aspects of the drive signal. As seen in FIG. 3, ultrasound generator 26 may also use a conventional signal processor to analyze the response of handpiece 10 to the drive signal. The term "drive signal" as used here encompasses at least a signal useful solely for powering an ultrasonic handpiece, a signal useful solely for tuning or calibrating a handpiece, and a combination of such a power signal and such a tuning or calibration signal."
>
> "As shown in FIG. 2, broad spectrum signal source 28 generates drive signal 4 which is combined with drive signals 5 and 6 from torsional **single frequency source 30** and longitudinal **single frequency source 32**, respectively, in amplifier 34. Amplifier 34 delivers drive signal 36 to handpiece 10 and to FFT DSP 38. FFT DSP 38 also receives feedback signal 40 from handpiece 10. FFT DSP 38 processes drive signal 36 and feedback signal 40 in the manner more fully disclosed in commonly owned U.S. patent application Ser. No. 08/769,257 (corresponding to PCT Patent Application No. PCT/US97/15952), the entire contents of which being incorporated herein by reference, to determine the operating characteristics of handpiece 10." (Emphasis added.)

In Applicant's claimed system, one electrical generator excites the electro-mechanical transducer at a single frequency to produce combined LT motion in the tip shaped to separate resistant tissue, the tip connected to the LT resonator.

As repeatedly discussed in the present specification, one of the principal advantages of Applicant's claimed L-T resonator is simultaneous torsional and longitudinal motion using only one electrical generator supplying alternating electrical voltage and current the L-T transducer. Boukhny's device must have two generators that are shown therein to operate at two different frequencies simultaneously, a fact that is clearly recognized and stated in the specification and abstract. Thus the motions, torsional and longitudinal, are not and can not be executed by one electrical generator at the same frequency and do not constitute one motion but, rather, two separate motions. Contrary to the Examiner's position there is no frequency synchronism in Boukhny because of the two frequencies are necessary.

Also, because in Boukhny's device, these motions are separate and occur at different frequencies the nodes of motion on the hand piece are located at different points. As a practical matter, which must concern anyone commercializing such surgical instruments, the devices are made useful for surgical purposes by positioning them within an easily controlled hand piece. The hand piece only remains essentially vibration free if the resonator is fastened or mounted to the hand piece at a node of motion that is stationary with respect to the hand piece. Mounting the resonator at the node assures that no resonance is transmitted to the surgeon's hand. Hence in Boukhny, if the fastening is made at nodes of longitudinal motion, then it will not be so fastened for torsional motion, and vice versa. This distinction is a very important practical matter, both for the surgical operator of the instrument and for minimizing the power lost in heat from friction in providing the motion. The expected result from two asynchronous simultaneous motions does not have the same efficiency, tissue dissection effect or efficacy, as does one L-T motion produced by one generator driving one transducer as Applicant claims.

A fair assessment of the disclosure in Boukhny has a system that only provides L and T motion with two generators operating at two different frequencies driving a transducer with two different sets of nodes, not Applicant's L-T motion at a single frequency with one unique set of L-T motional nodes. Applicant's single angled arrow depicts combined L-T motion. Such an arrow was not and could not be used to describe the motion provided by Boukhny as it has two separate, independent motions driven by two generators operating at different frequencies, one for purely torsional and the other for purely longitudinal.

The Examiner has rejected claims 4, 7, 8 and 11 under 35 USC 103(a) as being unpatentable over Boukhny, U.S. Patent 6,077,285 in view of Banko et al. U.S. Patent 3,589,363. The Examiner explains that, Boukhny discloses an ultrasonic device substantially as claimed except for: a source of irrigation fluid/vacuum source connected to said resonator. The Examiner finds that Banko et al. discloses the utilization of suction and irrigation in the same field of endeavor to aid in the removal of unwanted particles. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Boukhny using the irrigation and suction means as disclosed by Banko for removal of unwanted particles.

Banko does not teach this combination for torsional and longitudinal motion executed in frequency synchronism at a single frequency as Applicant claims, nor does it teach the efficacious resistant biological tissue dissection results that are obtained in combining irrigation, aspiration and L-T ultrasonic motion, an efficacy which Applicant's specification emphasizes.

Aside from the fact that Banko does not disclose I/A in combination with L-T vibration, the '363 patent clearly states that the device is intended for the removal of "...soft, yielding material....", in Column 1, lines 51-54. Hence Banko does not describe the removal of resistant tissue such as bone or tissue, such a collageous tissue, resistant to vibration. Such resistant tissue separation and removal in Applicant's specification and reply to the first action was discussed as possible by using combined longitudinal and torsional vibration. It would not

have been obvious that by changing the type of vibration at a single frequency in conjunction with I/A that such a result could be accomplished.

In addition to the absence of discussion of anything but the removal of gelatinous eye tissue and elastic tissue such neurologic tissue, and for which the Banko device and all predecessor devices as described therein are unsuitable. No reference discusses the further enhancement for resistant tissue separation and removal that is obtained with the use of the new and herein claimed combined L-T vibration at a single frequency with I/A.

The Applicant wants the Examiner to know what a skilled artisans has written about the tissue separation, cutting, removal, dissecting, etc. In *Ultrasonic Energy in Laproscopic Surgery*, Amarai, Joseph et al. at the Department of Surgery, Brown University, Providence Rhode Island Surgery Technology International III University Medical Press, 1994, pp. 156-157.

> **"The UCA (Ultrasonic Cavitational Aspirator, CUSA™ System, Valleylab, Inc., or Ultra™ Ultrasonic Aspirator, Sharplan Lasers, Inc.) is tissue selective, resulting in safe dissection of high water content tissues, with preservation of nerves, arteries and other collagen-rich (water sparse) structures. This is because collagenous tissues (blood vessels, nerves, ureters) require considerably more energy to fragment that high water content tissues such as liver, tumors and spleen.** This UCA is useful and safe in open surgical procedures such as tumor debulking, neurosurgery, and liver surgery. More recently, laparoscopic applications have been identified, including laparoscopic cholecystectomy and colectomy. Although limited in its scope of use laparaocscopically, it is an excellent tool for skeletonizing tissue. It is particularly useful in dissection Calot's triangle, in the presence of adipose tissue or acute inflammation (edema) and for skeletonizing the mesentery during colectomy. The UCA has also been used to shell the gallbladder off the liver bed. However, in this application a tendency exists for the UCA to dissect the collagen sparse liver bed

itself. **Furthermore, it leaves collagenous tissue strands and blood vessels intact. Since the UCA is not a good cutting or coagulating tool, other modalities such as electrosurgery are necessary for complete hemostasis, and scissors for cutting.** In this regard, electrosurgery has been added to some laparascopic UCA (CUSA, CEM Valleylab, Inc.) to limit instrument changes."

Emphasis in bold has been added to the above cited passage by the Applicant to show that there was at the time of the invention biological tissue resistant to commercial ultrasonic instruments and that resistance served a useful purpose. The present disclosure and claims address particular surgical needs different from that known in the past. The Applicant's claimed instrument was not obvious or expected and it is thus patentable.

The claims have been amended in accord with the disclosure as filed and minor structure included to add detail to the claims as presented and argued in reply to the first action and the claims have not been amended to require further searching but now could not be said to lack the structural support for, "frequency synchronism". The claims as amended have been distinguished over the cited references, reconsideration and prompt allowance are respectfully requested. Applicant's attorney will gladly discuss anything the Examiner want to have considered.

On behalf of the Applicant, Wuchinich by his attorney,

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